NOV 20 2008

510(k) Summary (REVISED) - K082628 cmr^{42} Cardiac MR Software Application

Submitter's Name	Circle Cardiovascular Imaging Inc.
Address	Suite 130, 3553 31 Street NW, Calgary, AB, Canada T2L 2K7
Establishment Registration Number	Not available
Date of Summary	November 05, 2008
Telephone Number **Fax Number**	1 403 775 1857 1 403 270 2384
Email	shirantha@circlecvi.com
Contact Person	Shirantha Samarappuli
Name of the Device	cmr^{42}
Common or Usual Name	Image Processing System
Classification Name	Classification Name: Picture Archiving and Communications System Device Class: II Product Code: LLZ Regulation Number: 21 CFR 892.2050
Indications for Use	cmr^{42} is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables; • Importing Cardiac MR Images in DICOM format • Supporting clinical diagnostics by qualitative analysis of the cardiac MR images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases. • Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR images, specifically distance, area, volume and mass • Supporting clinical diagnostics by using area and volume measurements for measuring LV function and

derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR images.
- Flow quantifications based on velocity encodes images

It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cmr[42] is a software application that can be used as a stand-alone product or in a networked environment.

The target population for the cmr[42] is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the device for certain sectors of the general public.

cmr[42] shall not be used to view or analyze images of any part of the body except the cardiac magnetic resonance images acquired from a cardiovascular magnetic resonance scanner.

Identification of the Legally Marketed Device (Predicate Device)

MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS)
Classification Name: System, Nuclear Magnetic Resonance Imaging
Device Class: II
Product Code: LNH
Regulation Number: 21 CFR 892.1000
510k #: K994283

MRI-Flow Analytical Software (FLOW)
Classification Name: System, Nuclear Magnetic Resonance Imaging
Device Class: II
Product Code: LNH
Regulation Number: 21 CFR 892.1000
510K #: K994282

Device Description

cmr[42] is a dedicated software application for evaluating cardiovascular images in a DICOM Standard format. The software

can be used as a stand-alone product that can be integrated into a hospital or private practice environment. cmr[42] has a graphical user interface which allows users to qualitatively and quantitatively analyze cardiac images for volume/mass, and flow quantification. It provides a comprehensive set of tools for the analysis of Cardiovascular Magnetic Resonance (CMR) images.

510(k) SUMMARY, continued

Indications for Use Comparison

DEVICE	INDICATIONS FOR USE
cmr[42] CARDIAC MR SOFTWARE K082628	cmr[42] is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format. It enables; • Importing Cardiac MR Images in DICOM format • Supporting clinical diagnostics by qualitative analysis of the cardiac MR images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases. • Supporting clinical diagnostics by quantitative measurement of the heart and adjacent vessels in cardiac MR images, specifically distance, area, volume and mass • Supporting clinical diagnostics by using area and volume measurements for measuring LV function and derived parameters cardiac output and cardiac index in long axis and short axis cardiac MR images. • Flow quantifications based on velocity encodes images It shall be used by qualified medical professionals, experienced in examining and evaluating cardiovascular MR images, for the purpose of obtaining diagnostic information as part of a comprehensive diagnostic decision-making process. cmr[42] is a software application that can be used as a stand-alone product or in a networked environment. The target population for the cmr[42] is not restricted, however the image acquisition by a cardiac magnetic resonance scanner may limit the use of the device for certain sectors of the general public. cmr[42] shall not be used to view or analyze images of any part of the body except the cardiac magnetic resonance images acquired from a cardiovascular magnetic resonance scanner.

DEVICE	INDICATIONS FOR USE
MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS) **K994283**	MASS, including its option, has been developed for the objective and reproducible analysis of multi-slice, multi-phase left and right ventricular function from cardiac MR data sets. The software enables the display of images for use by trained medical personnel. Intended purposes are: 1. Supporting clinical diagnoses about the status of the global and regional function and anatomy of the cardiac chambers; 2. Supporting the subsequent clinical decision making processes; 3. Supporting the use in clinical research trials, directed at studying changes in function and anatomy of the heart chambers as a result of interventions;
MRI-FLOW ANALYTICAL SOFTWARE **K994282**	Flow has been developed for the objective and reproducible analysis of velocity-encoded cine MR imaging studies of arterial vessels and heart valves. Intended purposes are: 1. Supporting clinical diagnoses about the status of the function of the cardiac cambers; 2. Supporting clinical diagnoses about the status of the flow velocity and volume flow through cardiac and peripheral vessels, both under basal and increased flow conditions; 3. Supporting subsequent clinical decision making purposes; 4. Supporting the use in clinical research trials, directed at studying changes in function of the heart chambers and in the flow through cardiac and peripheral vessels as a result of interventions.

510(k) SUMMARY, continued
Device Comparison Table

	Submission cmr[42] Cardiac MR Software K082628	**Predicate** MRI-MAGNETIC RESONANCE ANALYTICAL SOFTWARE SYSTEM (MASS) K994283	**Predicate** MRI-Flow Analytical Software K994282
Images from all MRI scanner vendors supported	X	X	X
Workstation operating system	MacOS, Microsoft Windows	Microsoft Windows, Unix, Linux	Microsoft Windows, Unix, Linux
Import and display magnetic resonance images	X	X	X
DICOM compliant networking	X	X	X
Images can be displayed by study and series	X		
Store images	X	X	X
Quantitative assessment of cardiac function	X	X	X
Task specific modules with corresponding tool sets	X		
Analysis of velocity-encoded images	X		X
Dynamic display of ventricular contractions	X	X	
Reports containing visualization of images and quantitative parameters	X	X	X
Analyzes long and short-axis views of the heart for quantitative assessment of cardiac function	X	X	

510(k) SUMMARY, continued

Description and Conclusion of Testing

Testing:

cmr[42] have been tested according to the specifications that are documented in a Master Software Test Plan. Testing is an integral part of Circle Cardiovascular Imaging Inc software development process as described in the company's product development process.

Conclusion:

The successful non-clinical testing demonstrates the safety and effectiveness of the cmr[42] when used for the defined indications for use and demonstrates that the device for which the 510(k) is submitted performs as well as or better than the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Shirantha Samarappuli
Director-Regulatory Affairs & Quality Assurance
Circle Cardiovascular Imaging, Inc.
Suite 130, 31 Street NW
Calgary, Alberta, T2L 2K7
CANADA

NOV 20 2008

Re: K082628
Trade/Device Name: cmr^{42} Cardiac Magnetic Resonance Imaging Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Samarappuli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082628

Device: cmr^{42} Cardiac Magnetic Resonance Imaging Software

Indications for Use:

cmr^{42} is intended to be used for viewing, post-processing and quantitative evaluation of cardiovascular magnetic resonance (MR) images in a Digital Imaging and Communications in Medicine (DICOM) Standard format.
It enables;

- Importing Cardiac MR Images in DICOM format
- Supporting clinical diagnostics by qualitative analysis of the cardiac MR images using display functionality such as panning, windowing, zooming, navigation through series/slices and phases.
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082628